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**U.S. FOOD AND DRUG ADMINISTRATION CLEARS
PERSONAL LUBRICANT FOR MARKETING**

New Product from Instead, Inc. Shows Promise for Women

La Jolla, CA (September 9, 2004) – The U.S. Food and Drug Administration (FDA) has granted Instead, Inc. clearance to market its personal lubricant product, Amphora™. In addition to its lubricating properties, Amphora has been shown, in early clinical and pre-clinical tests, to immobilize sperm for up to eight hours when applied vaginally by women, and, in laboratory testing, to inactivate certain sexually transmitted infection-causing organisms including gonococci (gonorrhea), herpes, chlamydia, and HIV.

Instead vice president and general manager, Teri Hirschfeld, said that while demonstrating the effectiveness of Amphora’s microbicidal properties will require full-scale clinical trials that will take years to conduct, the company hopes to receive clearance to market a new contraceptive device utilizing Amphora in the very near future. “We are currently conducting tests combining Amphora with a version of our Instead® Softcup®,” she explained. “This combination could provide women with a safe and discreet over-the-counter barrier contraceptive. Most importantly, it would put women in control.

“We also believe that Amphora has the potential to replace N-9,” Hirschfeld said. N-9 (Nonoxynol-9) is currently the only available spermicide in the U.S., and has been shown in a report jointly published by the World Health Organization (WHO) and the Contraceptive Research and Development program (CONRAD) to increase the potential risk of HIV and other sexually transmitted infections by damaging vaginal cells. Based on these findings, in early 2004 several major condom manufacturers announced plans to remove N-9 from their products.

Amphora (clinically known as Acidform) is an “acid-buffering” gel that coats the vaginal wall and cervix to maintain a woman’s natural pH level between 3.8 and 4.2. It is also compatible with latex and polyurethane condoms. Originally created by the Topical Prevention of Conception and Disease (TOPCAD) program, Amphora was licensed to Instead in 2002, and patent protection was granted in March 2004.

TOPCAD executive director, Lourens J.D. Zaneveld, DVM, Ph.D., who led the development of Amphora while on the faculty at Rush University Medical Center in Chicago, IL, said Amphora’s bio-adhesive and acid-buffering qualities are key to the product’s effectiveness and promise as a future microbicide. “Sperm and many STI-causing microbes, including HIV, are disabled at the natural pH level present in a woman’s vagina,” said Dr. Zaneveld. “Semen changes this balance, making the environment hospitable for both sperm and certain microbes. Amphora has been designed to maintain a woman’s natural pH in the presence of semen.” Thus, by merely preserving a woman’s natural defenses, Amphora potentially offers a completely safe and healthy means of protecting women from unwanted pregnancies and STI’s.

According to data from the Global Campaign for Microbicides, Amphora is one of 62 compounds under investigation as possible microbicides and one of fewer than a dozen that have conducted initial clinical trials. Its clearance by the FDA as a personal lubricant makes it the only one able to be marketed for human use.

About Instead, Inc.

Instead, Inc. provides women with new and different choices for greater freedom and control of their reproductive and sexual health. The San Diego-based company is dedicated to offering women better options in health care segments where their needs are underserved with products that are thoroughly tested for safety and efficacy. Instead has focused research and development efforts on period protection and feminine hygiene, contraception, prevention of sexually transmitted infections including HIV/AIDS, and other conditions where vaginal therapy can be an effective preventative or treatment. More information about Instead and its products is online at www.softcup.com.

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